

CMS Council on Technology and Innovation

Monday, February 14, 2005

Remarks by Dr. Stephen Hammill, MD, President, Heart Rhythm Society

I want to thank Dr. Tunis for inviting me to make comments during this important forum. I wish to begin by thanking Sean Tunis, Steve Phurrough, Marcel Salive, Joseph Chin, and Joanna Baldwin from CMS. As a representative of the Heart Rhythm Society, I have worked closely with these individuals over the past two years to expand coverage for primary prevention ICDs following the publication of MADIT II and SCD-HeFT. I have been extremely impressed with the willingness of CMS to work with the professional community. We have developed a comfortable relationship achieving an open dialogue which clearly will improve the care of Medicare beneficiaries who are at risk for sudden cardiac death.

CMS has chosen to tie expanded ICD coverage to a registry to help answer questions on ICD use. In September, CMS asked the Heart Rhythm Society to assemble a working group to discuss the merits and implementation of a national registry. The group was comprised of members from HRS; ACC; Heart Failure Society; Biotronik, Guidant, Medtronic, and St. Jude; several at-large members with expertise in registries; and observers from CMS and FDA. We sent a report to Dr. Tunis and Dr. Phurrough on November 22 which included a majority and minority opinion so please review the report for the full details.

The working group stated that the registry should be based upon two principles:

First. The primary focus of the registry is to measure outcomes and quality in a non-punitive environment leading to improvement of the care of patients receiving ICDs for primary prevention therapy.

Second. The registry should have qualities that include assurance of accurate data which would include training and education of individuals entering the data; clinical and technical support at the provider hospital; assessment of completeness of data entry; consistency of data evaluation; and onsite auditing to ensure accurate data submission.

The group recommended the use of a nationally recognized set of data standards and data definitions such as the ACC/ AHA/HRS data set elements and standard definitions for electrophysiology. The group also unanimously supported that the registry should be professionally driven and managed by professional medical organizations and that all stakeholders should have access to the data.

The published trials of ICD therapy have proven that this technology is effective when used in the setting of randomized controlled clinical trials. The question is can the results from the controlled trials with restricted entry criteria for patients, physicians, and institutions and the superior care that patients enrolled in trials receive be generalized to the expanded number of hospitals and providers who will be implanting the devices.

We recommended that the principle questions tested by the registry should include an assessment as to how the clinical characteristics, indications for ICD implantation, and in-hospital procedure-related complications for registry patients compare to those in primary prevention randomized clinical trials. We also recommended that certified providers competent in ICD implantation should be implanting ICD devices in registry patients and we outlined national measures that could be used to certify competency in ICD implantation.

An unresolved issue with the collection of registry data is the question of IRB approval. Collecting the data for payment and quality purposes does not require IRB approval as it falls under healthcare operations in the HIPAA regulations. However, when the CMS data collected by the QNET system is merged with longitudinal data entered in the second phase of the registry then patient identifiers would most likely be required with some type of limited IRB approval or consent. It would be quite unfortunate to have the informed consent process become a major stumbling block to entering patients and thus preventing patients from receiving primary prevention ICD therapy and being followed in the registry

To summarize, I believe that the success of a national registry depends upon the acceptance by all key stakeholders. The Heart Rhythm Society and the American College of Cardiology have strongly supported development of a registry to follow ICD patients, and we have expressed this support in the public press and with letters to our members. We have begun development of a national ICD registry based upon the ACC National Cardiovascular Data Registry, the NCDR, which has been in place since 1998 and now involves more than 550 cardiac catheterization laboratories. We believe the majority of ICDs are also implanted in these same hospitals. We support one ICD registry to limit the number of separate data entries required by hospitals and to help decrease the burden and cost to hospitals. The nation's hospitals should view this initiative as a tool to improve quality and not simply as an additional regulatory burden. I believe that participating hospitals should have access to an online data entry tool, using one entry form, submitted to a single location to help reduce the clerical burden on the hospital staff. I also believe that participants should have access to clinical and technical support personnel to ensure the data submitted are complete, consistent, accurate, and timely.

I am impressed that CMS is appropriately focused on quality and I look forward to working with CMS to develop the registry in a way that provides useful information that is reliable and accurate to improve the quality of care of Medicare beneficiaries receiving ICDs. Thank you.

SC Hammill
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Remarks by Alex Clyde, VP, Health Policy and Payment, Medtronic Inc.

Thank you for the invitation to present at this Open Door Forum. Medtronic has four areas of recommendations for issues the draft guidance should address based on our experience as the requestor for the recent NCD to expand covered indications for implantable cardioverter defibrillators (ICDs). The four areas of recommendations to include in guidance are – first to maintain patient access as an overriding priority, second to establish a consultative process, third to establish clear goals, and fourth to address implementation issues. Medtronic is pleased to work with CMS on these issues in the context of both the ICD decision and the larger policy debate. We understand the value of the endeavor, the enormity of the task, and that industry needs to be a valued partner.

Patient Access

Our first recommendation is that CMS ensure in guidance that maintaining patient access while any specific data collection mechanisms become established be an overriding priority for this initiative. Without sophisticated HIT systems, registries and other data collection mechanisms can take months to a year to establish, especially for high-volume services. For example, in the ICD decision, CMS handled this potential delay by utilizing an existing data exchange mechanism between CMS and the QIOs in order to meet its statutory timeframes for coverage. However, it's not clear that this approach would be generalizable to other NCDs. If CMS can work with stakeholders to ensure that the initiative to link data collection to coverage will not impede timely patient access, many of the other issues will be easier to work through.

Consultative Process

Our second recommendation is to establish a consultative process to develop the guidance document. This meeting is a great first step, but in order to ensure that the guidance will be usable and accomplish the Agency's goals, many constituencies should be engaged in a structured and iterative process with CMS. CMS should consider convening an active working group of interested stakeholders representing all parts of the health care delivery chain to assist the Agency in drafting the guidance document.

We also believe that, once an overall framework is established, there will need to be provisions in the guidance to create specific working groups for any data collection requirements proposed for specific NCDs – much as CMS established with the workgroup led by the Heart Rhythm Society for the ICD decision.

Goals, Funding, and Data Access

Our third recommendation would be that, before discussing appropriate applications of this new approach, CMS address head-on some of the important overarching issues of goals, funding, and data access. CMS should clearly state its goals and intentions for use of the data collected as part of the coverage process in the draft guidance. The guidance should define the types of clinical and operational research questions that need to be answered by tying data collection to coverage policy as opposed to those that might better be answered through other voluntary private and public sector mechanisms. For example, CMS should clarify whether data collection is integral to what makes the

service “reasonable and necessary,” whether data are necessary to monitor implementation the coverage policies, or whether data are sought to increase knowledge about the value of a service and optimal use. Achieving consensus on goals would establish an important foundation for a discussion of the types of technologies to which this new framework should apply, the kinds of data collection methods which should be used, and how the data should be shared with the public in order to ensure that the goals are achieved.

In terms of funding, CMS should identify appropriate stakeholders to establish a framework for funding the collection and analysis of the data. If CMS envisions a cost sharing model that includes the private sector, there should be a process to establish who will convene the various parties when there are multiple stakeholders and competitors as well as how decisions will be made concerning who will pay what share. In the case of ICDs, the manufacturers agreed among themselves to fund a registry for populations that might not have otherwise been covered but the funding for the bulk of the patients who will ultimately be enrolled in other privately run registries is yet to be defined. These funding consultations should also include consideration of reimbursement for providers who will bear an additional data collection and reporting burden..

Implementation Issues

Our fourth and final category of issues to be addressed in guidance would include the types of implementation issues that you have outlined in the Open Door Notice. These would include issues like criteria for selecting technologies for this new process. Ideally, the definition of clear goals and the types of questions that need to be addressed by linking data collection to coverage will drive the criteria for selecting technologies. CMS should clarify in guidance that data collection be protocol driven and that specific timeframes be established for the duration of data collection and for periodic monitoring of the data to ensure that the data being collected are responsive to the research questions being asked and worthy of the costs. Manufacturers engage in a wide range of activities to refine the use of their products, better define appropriate indications, and enhance the understanding of the value of their products. We urge CMS to take into account initiatives such as ongoing registries when considering the need for an additional government-mandated data collection effort. In the case of ICDs, Medtronic and other manufacturers are currently engaged in numerous trials and registries to improve outcomes for ICD therapy. CMS has agreed that patients enrolled in these private sector registries should be exempt from the CMS data collection requirement, but providers will need an easy way to keep up with which registries have been approved by CMS and which have not.

One final but important point is that while CMS should work with stakeholders to develop a broad process and framework that is predictable, the process will also need to preserve flexibility for negotiations on specific NCDs. Even if manufacturers know early in the product development cycle what CMS’ data requirements are likely to be, the unique aspects of individual technologies will drive the ultimate design of data development and require consultation with multiple stakeholders.

We understand CMS' urgency and believe that, with the appropriate consultative process, all four of these types of issues could be addressed in the initial guidance. However, we do feel strongly that, in order to build broad support, CMS should not just address the fourth category of implementation issues without establishing the broader consultative framework for some of the bedrock issues of patient access, goals, funding arrangements and data access.

Thank you for the opportunity to present on this important topic.

Remarks by Carol A. Kelly, Executive Vice President, AdvaMed

Thank you for this open forum and the opportunity to provide the agency with an update as to where AdvaMed stands on addressing Medicare coverage decisions associated with added data collection requirements.

As we have suggested in prior meetings and correspondence with the agency, the good guidance process approach is an appropriate way to address critical issues important to both the agency and stakeholders.

At our December board meeting, AdvaMed created a special task force chaired by Sarah Wells of Boston Scientific to address coverage under protocol issues and develop draft principles and guidelines related to this program. The work of this special TF will be discussed at our board and related meeting March 2nd and 3rd in conjunction with our annual meeting.

Among the questions we are considering are these:

- Which technologies should not be subject to coverage under protocol?
- Which technologies could be subject to coverage under protocol?
- For those technologies that will be subject to coverage under protocol, how can we make that process faster, more efficient, more predictable?
- For any set of evidence questions and data collection plans, what is the value of the information collected? Will the answers to the evidence questions be actionable?
- What are the key issues with facility credentialing and physician standards?
- Who manages the additional data collection? Who funds it? Who analyzes and reports it? Who are the key stakeholders who should have a role in the data collection?

Once we have held our board and related meetings, we will provide to you in writing as soon as possible any relevant discussions/conclusions on these matters that our board is ready to convey.

Again, I appreciate your hosting this forum today.

Medical Device Manufacturers Association (MDMA) Statement

Hi Sean and Steve, my name is Jori Frahler and I am with the Medical Device Manufacturers Association. On behalf MDMA, a national trade association representing the innovative sector of the medical device market, I would like to thank CMS for taking the steps to develop a draft guidance document concerning Medicare coverage decisions associated with data collection requirements.

MDMA recognizes that coverage decisions must be based on the best and latest scientific evidence, and that CMS' goal in issuing coverage guidance is to create a clear and predictable process that is evidence-based. However, it is also important that patients have access to products that are the most effective and least costly as quickly as possible.

While MDMA recognizes the importance and the significance of linking data collection with coverage, as CMS did with its recent ICD decision, it is imperative that a balance is struck which meets the needs CMS has for data collection without being overly burdensome on innovative device manufacturers. The implications for increased data collection for small device companies could be consequential as such requirements can be costly.

Questions MDMA would like to propose are:

1. Has CMS come to a decision regarding the length of time CMS plans to collect data on a device post-market?
2. Will CMS place data collection requirements on all devices which seek a National Coverage Decision?

Thank you for consideration of these questions.

Text version of remarks by Randy Burkholder, Senior Director, Policy, Pharmaceutical Research and Manufacturers of America (PhRMA)

PhRMA supports the development of high-quality information to improve patients' care and well-being. Empowering patients and physicians with high-quality information will help ensure that our health care system efficiently delivers the best possible results for all patients. Research from a range of sources in the public and private sectors already provides valuable information for patients and health care professionals in making treatment decisions.

PhRMA appreciates the initial opportunity that CMS is providing public stakeholders to offer input on its plans for a guidance document on coverage and evidence. CMS' effort holds potentially far-reaching implications for beneficiary access to therapies under Medicare Parts A and B. We look forward to working with CMS in this area.

Our specific questions are based on our review of recent national coverage memoranda, such as those on anticancer chemotherapy for colorectal cancer.

Key Questions:

Will CMS guidance result in restrictions in beneficiary access to FDA-approved medications?

CMS guidance on evidence should not restrict beneficiary access to FDA-approved medicines. All new medicines are subject to very rigorous approval standards and should remain available to beneficiaries.

What are the questions that CMS is seeking to answer?

The earlier speakers today identified a spectrum of purposes that CMS-directed evidence collection might support. These purposes included providing more evidence to patients and physicians for individual treatment decisions; improving the quality of care; and providing additional data for Medicare coverage decisions.

PhRMA believes it is essential for CMS to spell out more clearly the precise ends that it is attempting to address. Though CMS officials have discussed evidence collection and coverage, we believe the agency should be more specific as to its purposes than it has been so far.

This uncertainty is illustrated in documents released by CMS, and in the agency's final decision memo on anticancer chemotherapy for colorectal cancer:

For example, CMS' document on "improving evidence development" released for this forum says CMS "is interested in supporting the development of better scientific evidence to ensure improved patient outcomes and efficient health care delivery." In its final coverage memo on anticancer chemotherapy for four colorectal cancer medicines, CMS says "it is imperative that adequate clinical trial data for off-label uses be made available to patients and providers for clinical decision-making and to policymakers."

PhRMA certainly supports the goal of ensuring that good evidence is available for decision making. However, the approach CMS takes in this area will have a major impact on beneficiary access to health care interventions, and it is therefore important for the agency to clearly explain how this interest relates to CMS policy making and the statutory authority supporting these policies.

Which decision-maker(s) is the guidance serving?

We assume CMS intends to use the guidance on evidence collection in making coverage decisions, but this has not yet been clearly articulated.

The reason this should be clearly articulated is that the evidence CMS needs to decide whether intervention should be covered for Medicare patients can be quite different from the evidence that physicians or patients value in making individual treatment decisions. We believe it is appropriate for CMS to focus on the evidence it needs to implement the Medicare national coverage process. The evidence CMS gathers for this purpose will be on a population basis and may not be applicable to a given patient's case or history. Overall, we believe the best approach is for the physician to be the locus of care rather than for care to be dictated by coverage policy.

Who will pay for collection of additional evidence?

We are concerned that extensive demands for additional data could impose additional R&D costs on pharmaceutical research companies at a time when the economics of the research and development of new medicines are high and still increasing. CMS should ensure that policy development in this area does not undermine efforts at HHS, FDA and NIH to reduce the cost and time to bring medical innovations to patients. Similarly, CMS should avoid government duplication of efforts underway in the private sector.

Key Points:

Expand beneficiary access

In seeking to gather evidence on medicines under Parts A and B, CMS should seek to do so in ways that expand beneficiary access to medicines wherever possible or, at a minimum, maintain current access. CMS should not impose restrictions on access to medicines approved by FDA.

Consider processes of care

CMS' notice asks for input relevant to technologies. However, as noted on CMS' web site, national coverage policy applies to "services, procedures and technologies." We believe CMS' guidance should look beyond technologies because some of the largest gains in quality can come through development of additional evidence on services and procedures of care that lead to improved patient outcomes.

This can be particularly important for improving patient outcomes and health care efficiency. For example, Dr. Clancy's agency, AHRQ, recently announced findings by one hospital network that a relatively simple discharge-medication program was associated with significant reductions in patient death and hospital readmission rates. With gaps in quality contributing to tens of thousands of deaths each year, evidence to help close these gaps could be some of the most important to seek.

Ensure deliberative process

We appreciate Dr. McClellan's remarks today concerning the opportunities for stakeholders to provide comments on the planned guidance document. However, we are concerned that CMS is operating on an artificially rapid timetable. We desire to work constructively with the agency in developing this policy, and we ask the agency to move in an open, deliberative manner that supports constructive dialogue with all stakeholders, particularly the physicians and patients that this policy will affect.

Working collaboratively with the agency requires time for stakeholders genuinely to deliberate so that they can provide input that is specific and meaningful. To this end, we would recommend that CMS:

- 1) Develop an effective, workable draft guidance that takes into consideration input received from stakeholders;
- 2) Establish sound, meaningful good guidance practices (GGPs). CMS should continue to build on the Federal Register notice it issued last September in order to develop guidance consistent with GGPs. The document on coverage and evidence will be the first guidance pursued by CMS under GGPs, and we encourage the agency to err on the side of openness and deliberation.
- 3) Provide a broader public forum for input and discussion. We strongly encourage CMS to provide a broader public forum for discussion, such as a Town Hall meeting, after the draft guidance is released.

Conclusion:

We appreciate CMS providing an initial opportunity for public input as it moves forward in this important area. We look forward to continuing to work with you in the coming months. Thank you.